

1 CLAIMS

2 What is claimed is:

3
4 Claim 1. A biopolymer marker selected from the group
5 consisting of sequence ID REPQVVTLPSPRE or
6 (-)XSVLTQPPSVSGAPGQR(V) or at least one analyte thereof
7 useful in indicating at least one particular disease
8 state.

9
10 Claim 2. The biopolymer marker of claim 1 wherein
11 said disease state is predictive of Alzheimers disease.

12
13 Claim 3. A method for evidencing and categorizing at
14 least one disease state comprising:

15 obtaining a sample from a patient;
16 conducting mass spectrometric analysis on said
17 sample;
18 evidencing and categorizing at least one biopolymer
19 marker sequence or analyte thereof isolated from said
20 sample; and,

21 comparing said at least one isolated biopolymer
22 marker sequence or analyte thereof to the biopolymer
23 marker sequence as set forth in claim 1;

24 wherein correlation of said isolated biopolymer

1 marker and said biopolymer marker sequence as set forth in
2 claim 1 evidences and categorizes said at least one
3 disease state.
4

5 Claim 4. The method of claim 3, wherein said step
6 of evidencing and categorizing is particularly directed to
7 biopolymer markers or analytes thereof linked to at least
8 one risk of disease development of said patient.
9

10 Claim 5. The method of claim 3, wherein said step
11 of evidencing and categorizing is particularly directed to
12 biopolymer markers or analytes thereof related to the
13 existence of a particular disease state.
14

15 Claim 6. The method of claim 3, wherein the sample
16 is an unfractionated body fluid or a tissue sample.
17
18

19 Claim 7. The method of claim 3, wherein said sample
20 is at least one of the group consisting of blood, blood
21 products, urine, saliva, cerebrospinal fluid, and lymph.
22

23 Claim 8. The method of claim 3, wherein said mass
24 spectrometric analysis is selected from the group

1 consisting of Surface Enhanced Laser Desorption Ionization
2 (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,
3 TOF-TOF, and ESI-Q-TOF or an ION-TRAP.
4

5 Claim 9. The method of claim 3, wherein said
6 patient is a human.
7

8 Claim 10. A diagnostic assay kit for determining
9 the presence of the biopolymer marker or analyte thereof
10 of claim 1 comprising:

11 at least one biochemical material which is capable of
12 specifically binding with a biomolecule which includes at
13 least said biopolymer marker or analyte thereof, and

14 means for determining binding between said
15 biochemical material and said biomolecule;

16 whereby at least one analysis to determine a presence
17 of a marker, analyte thereof, or a biochemical material
18 specific thereto, is carried out on a sample.
19

20 Claim 11. The diagnostic assay kit of claim 10,
21 wherein said biochemical material or biomolecule is
22 immobilized on a solid support.
23

24 Claim 12. The diagnostic assay kit of claim 10

1 including:

2 at least one labeled biochemical material.

3
4 Claim 13. The diagnostic assay kit of claim 10,
5 wherein said biochemical material is an antibody.

6
7 Claim 14. The diagnostic assay kit of claim 12,
8 wherein said labeled biochemical material is an antibody.

9
10 Claim 15. The diagnostic assay kit of claim 10,
11 wherein the sample is an unfractionated body fluid or a
12 tissue sample.

13
14 Claim 16. The diagnostic assay kit of claim 10,
15 wherein said sample is at least one of the group
16 consisting of blood, blood products, urine, saliva,
17 cerebrospinal fluid, and lymph.

18
19 Claim 17. The diagnostic assay kit of claim 10,
20 wherein said biochemical material is at least one
21 monoclonal antibody specific therefore.

22
23 Claim 18. A kit for diagnosing, determining risk-
24 assessment, and identifying therapeutic avenues related to

1 a disease state comprising:

2 at least one biochemical material which is capable of
3 specifically binding with a biomolecule which includes at
4 least one biopolymer marker selected from the group
5 consisting of sequence ID REPQVVTLPSPRE or
6 (-)XSFLTQPPSVSGAPGQR(V) or at least one analyte thereof
7 related to said disease state; and

8 means for determining binding between said
9 biochemical material and said biomolecule;

10 whereby at least one analysis to determine a presence
11 of a marker, analyte thereof, or a biochemical material
12 specific thereto, is carried out on a sample.

13
14 Claim 19. The kit of claim 18, wherein said
15 biochemical material or biomolecule is immobilized on a
16 solid support.

17
18 Claim 20. The kit of claim 18 including:
19 at least one labeled biochemical material.

20
21 Claim 21. The kit of claim 18, wherein said
22 biochemical material is an antibody.

23
24 Claim 22. The kit of claim 20, wherein said labeled

1 biochemical material is an antibody.

2
3 Claim 23. The kit of claim 18, wherein the sample is
4 an unfractionated body fluid or a tissue sample.

5
6 Claim 24. The kit of claim 18, wherein said sample
7 is at least one of the group consisting of blood, blood
8 products, urine, saliva, cerebrospinal fluid, and lymph.

9
10 Claim 25. The kit of claim 18, wherein said
11 biochemical material is at least one monoclonal antibody
12 specific therefore.

13
14 Claim 26. The kit of claim 18, wherein said
15 diagnosing, determining risk assessment, and identifying
16 therapeutic avenues is carried out on a single sample.

17
18 Claim 27. The kit of claim 18, wherein said
19 diagnosing, determining risk assessment, and identifying
20 therapeutic avenues is carried out on multiple samples
21 such that at least one analysis is carried out on a first
22 sample and at least another analysis is carried out on a
23 second sample.

24

1 Claim 28. The kit of claim 27, wherein said first
2 and second samples are obtained at different time periods.
3

4 Claim 29. Polyclonal antibodies produced against a
5 marker sequence ID selected from the group consisting of
6 sequence ID REPQVVTLPSSRE or (-)XSVLTQPPSVSGAPGQR(V) or at
7 least one analyte thereof in at least one animal host.
8

9 Claim 30. An antibody that specifically binds a
10 biopolymer including a marker selected from the group
11 consisting of sequence ID REPQVVTLPSSRE or
12 (-)XSVLTQPPSVSGAPGQR(V) or at least one analyte thereof.
13

14 Claim 31. The antibody of claim 30 that is a
15 monoclonal antibody.
16

17 Claim 32. The antibody of claim 30 that is a
18 polyclonal antibody.
19

20 Claim 33. A process for identifying therapeutic
21 avenues related to a disease state comprising:

22 conducting an analysis as provided by the kit of
23 claim 18; and

24 interacting with a biopolymer selected from the group

1 consisting of sequence ID REPQVVTLPSSRE or
2 (-)XSVLTQPPSVSGAPGQR(V) or at least one analyte thereof;
3 whereby therapeutic avenues are developed.
4

5 Claim 34. The process for identifying therapeutic
6 avenues related to a disease state in accordance with
7 claim 33, wherein said therapeutic avenues regulate the
8 presence or absence of the biopolymer selected from the
9 group consisting of sequence ID REPQVVTLPSSRE or
10 (-)XSVLTQPPSVSGAPGQR(V) or at least one analyte thereof.
11

12 Claim 35. The process for identifying therapeutic
13 avenues related to a disease state in accordance with
14 claim 33, wherein said therapeutic avenues developed
15 include at least one avenue selected from a group
16 consisting of 1)utilization and recognition of said
17 biopolymer markers, variants or moieties thereof as direct
18 therapeutic modalities, either alone or in conjunction
19 with an effective amount of a pharmaceutically effective
20 carrier; 2)validation of therapeutic modalities or disease
21 preventative agents as a function of biopolymer marker
22 presence or concentration; 3)treatment or prevention of a
23 disease state by formation of disease intervention
24 modalities; 4)use of biopolymer markers or moieties

1 thereof as a means of elucidating therapeutically viable
2 agents, 5) instigation of a therapeutic immunological
3 response; and 6) synthesis of molecular structures related
4 to said biopolymer markers, moieties or variants thereof
5 which are constructed and arranged to therapeutically
6 intervene in said disease state.

7
8 Claim 36. The process for identifying therapeutic
9 avenues related to a disease state in accordance with
10 claim 35, wherein said treatment or prevention of a
11 disease state by formation of disease intervention
12 modalities is the formation of biopolymer/ligand
13 conjugates which intervene at receptor sites to prevent,
14 delay or reverse a disease process.

15
16 Claim 37. The process for identifying therapeutic
17 avenues related to a disease state in accordance with
18 claim 35, wherein said means of elucidating
19 therapeutically viable agents includes use of a
20 bacteriophage peptide display library or a bacteriophage
21 antibody library.

1 Claim 38. A process for regulating a disease state
2 by controlling the presence or absence of a biopolymer
3 selected from the group consisting of sequence ID
4 REPQVVTLPSPRE or (-)XSVLTQPPSVSGAPGQR(V) or at least one
5 analyte thereof.

continued